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PERIPHERAL NERVE STIMULATION FOR THE TREATMENT OF LOWER EXTREMITY PERIPHERAL NEUROPATHY IN A DIABETIC AMPUTEE CASE REPORT

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Background: Providing adequate analgesia for peripheral neuropathy in poorly controlled diabetics remains challenging, and effective invasive therapy increases the risk of infection and delayed wound healing. A peripheral nerve stimulator (PNS) is a beneficial treatment option for neuropathy. This case is IRB exempt from obtaining informed consent for publication. The report is de-identified in accordance with the Safe Harbor method. All 18 individual identifiers are removed, and there is no evidence to suggest that the information could be used alone or in combination with other information to identify the patient.

Case Report: A 29-year-old woman with a medical history of poorly controlled type-1 diabetes mellitus, despite multiple medications, presented to an outpatient clinic with left lower extremity neuropathic pain following a right below-knee amputation (BKA) secondary to sustaining a nonhealing right foot wound. The patient underwent a PNS trial for 4 days, which resulted in a decrease in her pain level by more than half. A left lower extremity wirelessly powered permanent PNS device was placed, which resulted in improved sleep, ability to walk longer distances, and an 88% reduction in pain.

Conclusions: PNS was safe and successful for left lower extremity neuropathy in a patient with poorly controlled diabetes and a right BKA.

Key words: Peripheral nerve stimulator, diabetes, neuropathy, case report

BACKGROUND

Diabetes mellitus is the leading cause of peripheral neuropathy worldwide and produces debilitating symptoms in this population (1). The painful symptomatology of peripheral neuropathy is termed neuropathic pain, typically presenting as paresthesia, hypoesthesia, hyperalgesia, and/or hypoalgesia (2). The complexity of symptoms and difficulty establishing successful pain control for patients suffering from diabetic peripheral neuropathic pain has led to a decreased quality of life and increased morbidity in this population (2). Early recognition and diagnosis of diabetic neuropathy are paramount to its prognosis. Once the diagnosis is made, the mainstay for the prevention of disease progression is focused on glycemic control with injectable and oral agents, followed by pain management (3). Initial treatment strategies for analgesia include topical analgesics, anticonvulsant drugs, antidepressants, opioids, physical therapy, and minimally invasive regional anesthetic nerve blocks (3,4,5). The aforementioned drugs are known to cause unwanted side effects that decrease quality of life, such as weight gain, somnolence, constipation, nausea, addiction, and more (3).

When deciding on the analgesic treatment approach for patients with poorly controlled diabetes, elective interventional procedures and implantation for neuromodulation are relatively contraindicated due to increased risk of incision site infection, implant complications, and impaired wound healing (6). Although glycemic control is vital for the management of peripheral

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diabetic neuropathy, patients with poorly controlled glucose control and a high hemoglobin A1C, despite multiple injectable and oral agents, rely on analgesic control to carry out activities of daily living (ADLs). We present a case that demonstrates the successful use of a wirelessly powered peripheral nerve stimulator (PNS) for peripheral neuropathy in the left lower extremity of a diabetic patient (Fig. 1) after undergoing a right below-the-knee amputation (BKA).

CASE REPORT

This case is IRB exempt from obtaining informed consent for publication. The report is de-identified in accordance with the Safe Harbor method. All 18 individual identifiers are removed, and there is no evidence to suggest that the information could be used alone or in combination with other information to identify the patient.

A 29-year-old woman with type-1 diabetes mellitus presented to our clinic with left lower extremity neuropathic pain following a right BKA secondary to sustaining a nonhealing right foot wound. She endorsed pain mostly on the lateral and medial aspects of her left lower calf that were dramatically affecting her basic ADLs. Prior to the patient's BKA, she had routine visits with her primary care physician, podiatrist, and endocrinologist to aggressively treat her foot wound and uncontrolled diabetes; however, high-dose insulin and oral agents continued to be suboptimal for her glycemic control and continued to be a factor in disease progression of her diabetic peripheral neuropathy. This resulted in a painful, nonhealing ulcer of the right foot, which ultimately led to amputation. The patient's hemoglobin A1C and glucose were improved after the BKA; however, left lower extremity peripheral neuropathic pain continued to increase despite analgesic treatment with traditional medications (i.e., gabapentin, pregabalin). The patient was not placed on opioid medications after shared decision-making given the patient's concern for side effects and the risk of addiction. Additionally, undesired and intolerable side effects from these medications warranted a different treatment approach. A diagnostic anesthetic injection, targeting the superficial left distal peroneal and saphenous nerves at the ankle, relieved the majority of her lateral and medial lower leg pain for ~36 hours, and the patient endorsed significant improvement in her pain while walking and improved her ability to sleep due to the decrease in pain.

Subsequently, after a lengthy discussion with the patient regarding the risks and benefits of the procedure, such as infection, the patient was considered a candidate for a PNS trial of the left lower extremity. Fluoroscopy, ultrasound, and palpation were used to plan the introducer entry point and route for two 8-contact trial stimulators, targeting the left superficial peroneal and superficial saphenous nerves. A 13-G introducer and then an 8-contact electrode array were directed at the superior portion of the medial malleolus. A second 13-G introducer was used to insert the second 8-contact electrode array along the lateral aspect of the leg, and place-

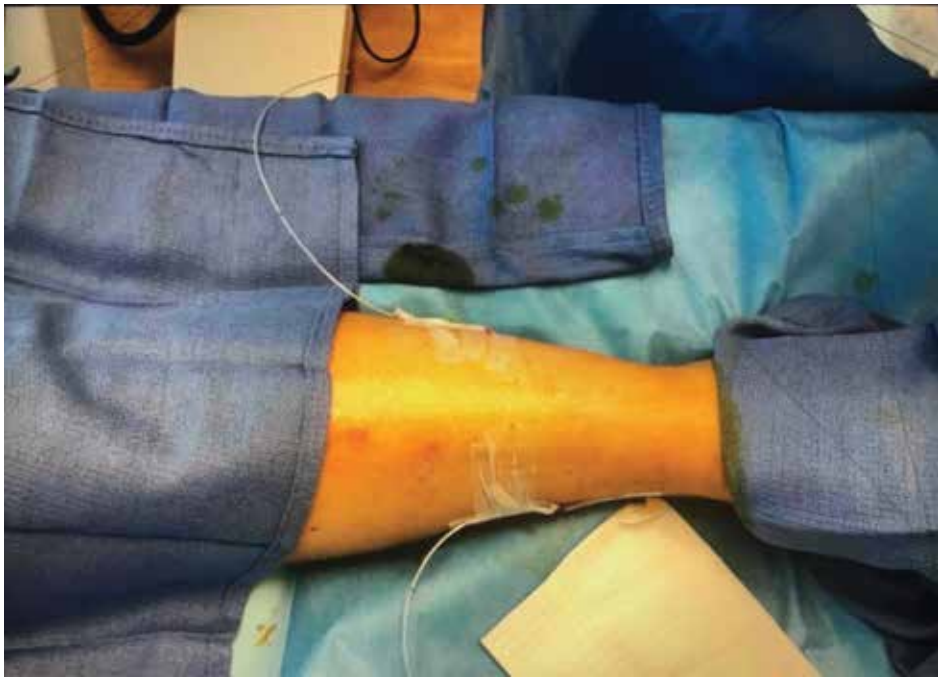

Fig. 1: Image showing the PNS trial stimulators in the left lower extremity.
PNS, peripheral nerve stimulator.

ment was confirmed with fluoroscopy to be at the anterior portion of the tibiofibular junction, with the electrode arrays viewed anterior to posterior. Ultrasound was utilized for initial entry of the introducers and electrodes, and fluoroscopy was utilized to confirm final anatomic placement (Fig. 2). The steering stylets were removed and receivers were inserted into the inner lumen of the electrode arrays. A trial stimulation was performed and the patient endorsed paresthesias on the plantar surface and dorsal aspect of the left foot. After stimulation was confirmed, the trial stimulators were knotted after the second marker band and were then secured to the skin with a liquid adhesive, adhesive bandages, and then completely covered under a sterile bio-occlusive dressing (Fig. 1). Minimizing the risk of infection in this patient was a priority, and given this specific scenario, a short PNS trial was performed and extensive oral antibiotics were provided to the patient. The PNS trial, although only 4 days long, yielded successful results with the patient reporting pain levels decreasing by more than half. After a thorough discussion, a joint decision between the physician and patient was made to schedule a permanent PNS implantation.

After removing the temporary PNS trial leads, permanent PNS leads were placed by making an incision at the previous entry sites and inserting two 4-contact, tined, permanent electrode arrays using the placement techniques used for the trail lead placement. The steering stylets were removed and the receivers were inserted into the electrode arrays. A receiver pocket was created and both stimulators were tunneled beneath the skin to the receiver pocket. A knot was tied to permanently mate the receivers and electrode arrays. The distal portion of the stimulators were coiled, sutured together to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and subcuticular sutures. The devices were programmed to obtain paresthesia-free stimulation, with parameters set to a frequency of 80 Hz, pulse width of 360 μs, and current of 3 mA.

On follow-up appointments, the patient reported an 88% reduction in her left lower extremity pain (Fig. 1), specifically reporting a gradual pain score reduction on the Numeric Rating Scale from 8/10 to 1/10 at 1 and 3 months, respectively, after the permanent PNS implant. The patient reported the ability to ambulate farther without the need to take frequent pauses due to pain, improved sleep, and an overall improved quality of life.

DISCUSSION

The gate-control theory of pain and the introduction of transcutaneous electrical nerve stimulation (TENS) devices supported the idea that nonnoxious stimuli to a painful area can decrease the perception of one's pain (7). Multiple studies (8,9) have proven TENS as an effective analgesic agent for diabetic peripheral neuropathic pain. An alternative and FDA-approved therapy for medically refractory diabetic peripheral neuropathy is spinal cord stimulation (SCS), which has been proven to be safe and effective (10). A less invasive and effective treatment modality for neuropathic pain is PNS. With the advent of wirelessly powered PNS devices, the procedure does not require a large pocket to be made surgically for the implanted power generator (IPG) as in previous PNS and SCS systems, making the procedure significantly less invasive and potentially decreasing implant-related infection rates (11,12).

Battery-related complications and pocket pain

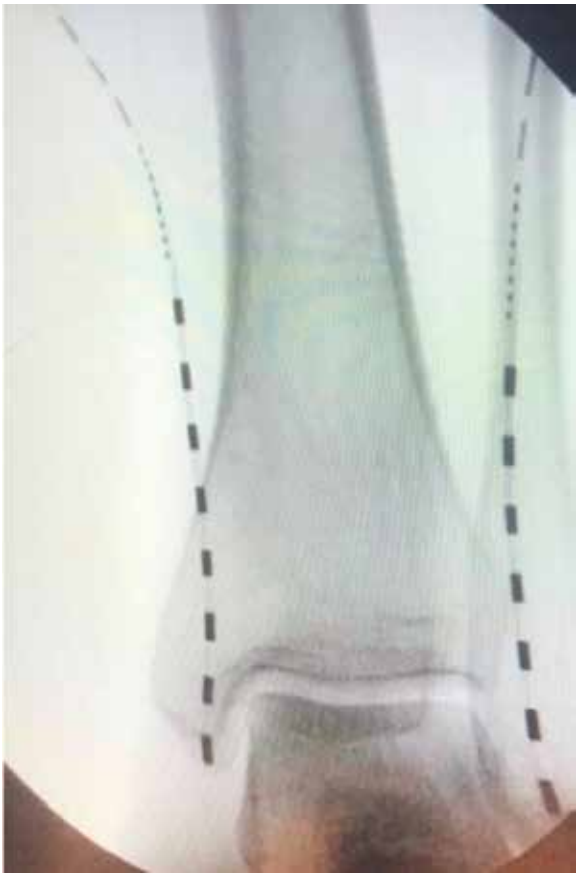

Fig. 2. Image showing the 8-contact electrode arrays at the peroneal and saphenous nerves.

from the IPG is practically omitted with the use of a wirelessly powered PNS device (11,13). Patients with poorly controlled diabetes and severe neuropathic pain are at increased risk of developing hardware-related infections with implantable devices. When considering invasive therapy for this specific patient population, neuromodulation in the form of wirelessly powered PNS devices for analgesia could substantially impact their quality of life and be a safer option than a standard PNS or SCS device. Careful patient selection and risks vs benefits of the invasive procedure should be reviewed and discussed with each patient. In this patient with a uniped and extreme pain, the PNS system dramatically improved her quality of life and was a successful option for analgesia of diabetic peripheral neuropathy.

CONCLUSIONS

A wirelessly powered, battery-free PNS was a successful option for this diabetic patient suffering from left leg neuropathic pain as a result of poorly controlled diabetes. This battery-free system offers advantages over standard PNS devices, devoid of complications associated with the bulk of an implantable pulse generator, and flexibility as related to device placement and programming protocols. Additionally, early consideration of a wireless PNS may aid in avoidance of opioids, as this patient was never placed on opioids.

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